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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,522	09/22/2003	Andre Stamm	107664.115 US13	5813

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,522	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *6,7,13,14,25-33,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-12,15-24 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/665,519.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Remarks, all filed 09/06/06 and the Information Disclosure Statements (IDS) filed 9/22/03; 6/18/04; 6/28/04; 3/31/05; 9/20/05; 5/8/06; and 6/19/06 is acknowledged. Receipt is also acknowledged of the Terminal Disclaimers filed 05/02/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any patent granted on Application Nos. 10/665,516; 10/665,517; 10/665,518; 10/665,519 and 10/290,333. Receipt is also acknowledged of the Terminal Disclaimers filed 05/02/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent Nos. 6,652,881; 6,589,552; 6,596,317; 6,277,405; 6,074,670 and 7,037,529.

Applicant's election with traverse of Group I (Claims 1-5, 8-12, 15-24 & 34-37) in the reply filed on 09/06/06 is acknowledged.

Claims 6, 7, 13, 14, 25-33, 38 and 39 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/06/06.

Claims 1-39 are pending in this action. Claims 6, 7, 13, 14, 25-33, 38 and 39 have been withdrawn. Claims 1-5, 8-12, 15-24 and 34-37 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtet *et al.* (U.S. Patent No. 4,895,726).

The instant invention is drawn to a fenofibrate composition with an enhanced bioavailability, whereby the required daily dose is lower than 200 mg.

Curtet *et al.* ('726) teach a pharmaceutical composition comprising fenofibrate having improved bioavailability, whereby the recommended amount of fenofibrate is about 200 mg per therapeutic unit. The fenofibrate composition can be administered only once a daily (see reference column 1, lines 22-27; 50-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8-12, 15-24 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet *et al.* (U.S. Patent No. 4,895,726) in view of Kerč *et al.* (U.S. Patent No. 6,042,847).

The instant invention is drawn to a fenofibrate composition with an enhanced bioavailability, whereby the required daily dose is lower than 200 mg.

The instant invention is also drawn to a fenofibrate composition with an enhanced bioavailability, whereby the required daily dose is lower than 200 mg and wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm

according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

Curtet *et al.* ('726) teach a fenofibrate composition having improved bioavailability, whereby the recommended amount of fenofibrate is about 200 mg per therapeutic unit. The fenofibrate composition can be administered only once a daily (column 1, lines 22-27; 50-51). The fenofibrate composition comprises fenofibrate granules in combination with a solid surfactant, wherein the fenofibrate and solid surfactant have been co-micronized; a hydrosoluble carrier and a hydrophilic polymer, wherein the fenofibrate/solid surfactant mixture granules have a mean particle size of less than 15 microns (see entire reference, particularly, column 1, lines 1-68); (col. 2, lines 1-68); examples and claims. Curtet *et al.* teach polyvinylpyrrolidone as the hydrophilic polymer employed. The hydrosoluble carrier taught can be lactose (col. 2, lines 1-12). The surfactant is selected from solid surfactants and may be an alkali metal sulfate of lauryl alcohol, for example, sodium lauryl sulfate (aka- sodium dodecyl-sulfate), which is the preferred surfactant, provided in a recommended amount of between 0.5% and 7% (col. 1, lines 52-58). Additional excipients include magnesium stearate (lubricant) and starch (disintegrant) (col. 2, lines 1-4).

The mean particle size of the fenofibrate is less than 15 microns, preferably less than 10 microns and particularly preferably less than 5 microns (col. 1, lines 50-66). The recommended amount will be between 0.5% and 7% by weight, relative to the total weight of the formulation. The weight ratio surfactant/fenofibrate will be between about 0.75/100 and 10.5/100 (col. 1, lines 52-60).

Curtet *et al.* teach various dissolution rates using a rotating-vane apparatus, wherein the dissolution medium comprises water and 0.1M sodium lauryl-sulfate (col. 3, lines 34-68 through col. 4, lines 1-63). The values and curve obtained after 20 minutes are plotted in Fig. 1. Additionally, Curtet *et al.* teach comparison results of T 50%, i.e., the time required for 50% of the fenofibrate to dissolve (col. 3, lines 52-60).

Curtet *et al.* do not teach the instant claimed percentages of drug but do teach effective amounts of fenofibrate, whereby the fenofibrate is present in an amount of 200 mg per therapeutic unit. Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the prior art teaches the use of the same drug (fenofibrate), employed once a day and used in similar amounts to achieve enhanced bioavailability of the drug.

While Curtet *et al.* do not expressly teach the instant dissolution rates, it is the position of the Examiner that suitable or effective dissolution rates can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results. In this instance, the prior art clearly teaches a similar fenofibrate composition having enhanced bioavailability and dissolution rates with a dissolution medium of water and 0.1M sodium lauryl-sulfate, similar to that claimed. Moreover, Applicant has not demonstrated any unexpected or superior results, which accrue from the claimed rates of dissolution. The prior art dissolution rates would be considered effective rates of dissolution.

Curtet *et al.* teach that the fenofibrate composition can be presented in the form of capsules. Curtet *et al.* do not teach that their granular fenofibrate composition is in the form of a *tablet.* It is familiar to one of ordinary skill in the art that such pharmaceutical compositions can be contained in various dosage forms, such as capsules, tablets, granules and the like. Such skill is also evident from the reference of Kerc *et al.* (see below).

Kerč *et al.* ('847) teach a three-phase fenofibrate pharmaceutical formulation for daily peroral application, wherein the composition can be in the form of tablets or capsules (see reference column 1, lines 18-22); (col. 4, line 34). Kerč *et al.* teach that the granulate of an active ingredient, the water-soluble polymer polyvinylpyrrolidone, cellulose ethers and other ingredients suitable for the preparation of solid pharmaceutical forms has good compressibility, so prepared tablets are firm, have low brittleness and make possible controlled release of active ingredient (col. 8, lines 54-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the fenofibrate formulations made by compression of granules to form tablets, such as taught by Kerč *et al.* within the fenofibrate compositions of Curtet *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Kerč *et al.* explicitly teach a fenofibrate pharmaceutical composition that can be in suitable forms, such as tablets and teach that the tablets have good compressibility, are less brittle and exhibit firmness. The expected result would be a fenofibrate tablet formulation having improved bioavailability for the beneficial treatment of high cholesterol conditions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

November 27, 2006

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